

K103818

NOV 16 2011

**510(k) Summary**

Submitted By:

Submitter: Ventana Medical Systems, Inc.  
 Contact: George De La Rosa  
 Date Prepared: November 15, 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K103818**

<b>Device Name</b>	CONFIRM anti-Progesterone Receptor (1E2) Rabbit Monoclonal Primary Antibody
	Common name: Antibody for aid in the detection of progesterone receptor (PGR) antigen in histological tissue sections
	Classification: Class II Non-exempt
	Product Code: MXZ
<b>Predicate Device</b>	CONFIRM anti-Progesterone Receptor (1E2) Rabbit Monoclonal Primary Antibody is substantially equivalent to DAKO North America's commercially available Monoclonal Mouse Anti Human Progesterone Receptor, Clone PGR 636
	K020023
<b>Device Description</b>	Ventana's CONFIRM anti-Progesterone Receptor (1E2) Rabbit Monoclonal Primary Antibody specifically binds to progesterone receptor antigen located in the nuclear region of a variety of normal and neoplastic tissues. The antibody is diluted in 0.05 M Tris-HCl with 2% carrier protein, and 0.1% ProClin 300, a preservative. There is trace (0.2%) fetal calf serum of U.S. origin from the stock solution. Total protein concentration of the reagent is approximately 10 mg/mL. Specific antibody concentration is approximately 1 µg/mL. CONFIRM anti-PR (1E2) is a rabbit monoclonal antibody produced as a cell culture supernatant.
<b>Intended Use</b>	<p>This antibody is intended for in vitro diagnostic (IVD) use.</p> <p>CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal (IgG) Primary Antibody is intended for laboratory use for the qualitative detection of progesterone receptor (PR) antigen in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer with VENTANA detection kits and ancillary reagents. CONFIRM anti-PR (1E2) is directed against an epitope present on human progesterone receptor protein located in the nucleus of PR positive normal and neoplastic cells. CONFIRM anti-PR (1E2) is indicated as an aid in the management, prognosis, and prediction of hormone therapy for breast carcinoma.</p> <p>This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.</p> <p>Prescription use only.</p>
<b>Summary of the new and predicate devices</b>	CONFIRM anti-PR (1E2) is a rabbit monoclonal antibody that recognizes the A and B forms of human progesterone receptor. The immunogen was developed from a synthetic peptide identified as an area of potential high antigenicity common to progesterone receptor A and B forms. The peptide was synthesized and covalently bound to keyhole limpet hemocyanin to further increase antigenicity. CONFIRM anti-PR (1E2) has been shown to react with 60 kD, 87 kD and 110 kD proteins from T47D

	<p>cells via Western blotting. The protein sizes are in agreement with the predicted molecular weight of progesterone receptor forms A, B and C.<sup>1,2</sup></p> <p>Dako FLEX Monoclonal Mouse Anti-Human Progesterone Receptor Clone PgR 636 consists of a mouse anti-human monoclonal antibody produced as a tissue culture supernatant is used in the qualitative detection of human progesterone receptor in tissue sections of human breast cancer by immunohistochemistry.</p> <p>Both products specifically bind to progesterone receptor proteins located in the nuclei of cells, and these products require similar detection chemistry principles for visualization of the product, and both aid in the prognosis of breast carcinoma.</p>
<b>Non-clinical performance data</b>	<p>Distribution of progesterone receptor throughout normal tissue has been reported in a variety of studies. The required panel of normal tissues was tested with this antibody as specified in the 6/3/98 final version of Guidance for Submissions of Immunohistochemistry Applications to the FDA. All tissues were formalin fixed and paraffin embedded.</p> <p>Non-clinical performance testing has been conducted to demonstrate performance characteristics of CONFIRM anti-PR (1E2). Results of tissue-specificity and precision testing are noted in the product package insert.</p>
<b>Clinical performance data</b>	<p>A randomized, multi-site, multi-reader study was conducted to compare the staining performance of the CONFIRM anti-PR (1E2) on the BenchMark ULTRA instrument and on the BenchMark XT instrument to that of the Dako FLEX Monoclonal Mouse Anti-Human Progesterone Receptor Clone PgR 636 Ready-To-Use (FLEX anti-PgR (636)) on the Dako Autostainer Plus.</p> <p>Approximately 120 negative and 216 positive cases of breast cancer, representing the clinical range of the assay, were randomly assigned to three study sites such that each site received an equal number of cases and each site received cases representing each clinical assessment category.</p> <p>For CONFIRM anti-PR (1E2) staining on the BenchMark ULTRA instrument compared to the FLEX anti-PgR (636) on the Dako Autostainer Plus, the positive, negative, and overall agreement rates (pooled across all testing sites) were greater than 85%. For CONFIRM anti-PR (1E2) staining on the BenchMark XT instrument compared to the FLEX anti-PgR (636) on the Dako Autostainer Plus, the positive, negative, and overall agreement rates were all greater than 85%. For CONFIRM anti-PR (1E2) staining on the BenchMark ULTRA instrument compared to the CONFIRM anti-PR (1E2) staining on the BenchMark XT instrument, the positive, negative, and overall agreement rates were all greater than 85%.</p>

<sup>1</sup> Bevitt DJ, Milton ID, Piggot N, Henry L, Carter MJ, Toms GL, Lennard TW, Westley B, Angus B, Horne CH. New Monoclonal antibodies to oestrogen and progesterone receptors effective for paraffin section immunohistochemistry. J Pathol. 1997;183(2):228-232.

<sup>2</sup> Dickson RB, Lippman ME. Genes, oncogenes, and hormones: advances in cellular and molecular biology of breast cancer. Kluwer Academic Publishers, Boston, 1992: 285-286



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Ventana Medical Systems, Inc.  
c/o Mr. George De La Rosa  
Manager, Regulatory Affairs  
1910 E. Innovation Park Drive  
Tucson, AZ 85755

NOV 16 2011

Re: k103818

Trade/Device Name: CONFIRM anti-Progesterone Receptor (1E2) Rabbit  
Monoclonal Primary Antibody

Regulation Number: 21 CFR § 864.1860

Regulation Name: Immunohistochemistry reagents and kits

Regulatory Class: Class II

Product Codes: MXZ

Dated: October 26, 2011

Received: October 27, 2011

Dear Mr. De La Rosa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

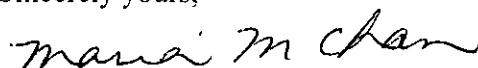
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of

Page 2 – Mr. George De La Rosa

substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Maria M. Chan". The signature is written in a cursive, flowing style.

Maria M. Chan, Ph.D.  
Director  
Division of Immunology and Hematology Devices  
Office of *In Vitro* Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number: K103818

Device Name: CONFIRM Anti-Progesterone Receptor (1E2) Rabbit Monoclonal Primary Antibody

This antibody is intended for in vitro diagnostic (IVD) use.

CONFIRM anti-Progesterone Receptor (PR) (1E2) Rabbit Monoclonal (IgG) Primary Antibody is intended for laboratory use for the qualitative detection of progesterone receptor (PR) antigen in sections of formalin-fixed, paraffin-embedded tissue on a VENTANA automated slide stainer with VENTANA detection kits and ancillary reagents. CONFIRM anti-PR (1E2) is directed against an epitope present on human progesterone receptor protein located in the nucleus of PR positive normal and neoplastic cells. CONFIRM anti-PR (1E2) is indicated as an aid in the management, prognosis, and prediction of hormone therapy for breast carcinoma.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

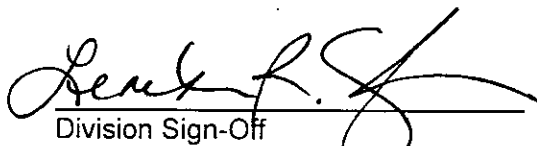
Prescription use only.

Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD).

  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)   K103818  

Page 1 of